APR 1 5 2002

510(k) SUMMARY

510(k) NUMBER: PENDING K020435

SUBMITTED BY: Applied Medical Resources Corporation
22872 Avenida Empresa
Rancho Santa Margarita, CA-92688
(949) 713-8000

CONTACT PERSON: Anil Bhalani
Vice President of Regulatory Affairs and Clinical Programs

DATE OF PREPARATION: February 6, 2002

NAME OF DEVICE: Wound Retractor

CLASSIFICATION NAME: Drape, Surgical, General & Plastic Surgery.
(Regulation Number 21CFR 878.4370, Surgical drape and drape accessories).

TRADE NAME: Wound Retractors

PREDICATE DEVICE: Dexterity Protractor (Protector Retractor and Protector Retractor with drape, K954824), Medical Creative Technologies, Inc. Colmar, PA.

SUMMARY STATEMENT: The Applied Wound Retractor is indicated for use to retract and protect an incision in the abdominal wall during both laparoscopic and open surgery. It is intended to allow the surgeon to access the abdominal cavity during surgery through an atraumatically retracted wound, providing maximum exposure with minimum incision size. In addition to incision retraction, it is intended to protect against wound contamination during both laparoscopic and open surgery.

Applied's Wound Retractors come in four sizes, small, medium, medium-large and large and in two shapes, round and elliptical. The shape of a wound retractor is defined by its wound retracting ring. The Wound Retractor consists of a wound retractor ring and a wound protecting sheath. The wound retractor ring is molded from a plastic material. The wound protecting sheath is comprised of a cylindrical elastic sheath with a ring at one end. The Wound Retractor package also includes an incision template.

The Wound Retractor is simple to set up and easy to use. Using a sterile skin marker an incision line is marked at the surgery site. Once the incision is made the wound protecting sheath is placed in position through the incision with the ring inside the abdomen. The wound retractor ring is then placed on the abdomen and attached to the wound protecting sheath. Once securely in

place, the Wound Retractor keeps the incision open or retracted during clinical procedure. The wound protective sheath lines the wound or incision and protects its from contamination and injury from instruments during the surgical procedure.

The Wound Retractors is a disposable, single-use device and is packaged inside Tyvek/Mylar peel pouch, which is standard packaging material for medical products. The packaged product will then be packaged in an outer product carton in 1 to 10 pieces per carton.

The Wound Retractors is substantially equivalent to predicate devices in design methodology, principle of operation and clinical utility. The Wound Retractors introduces no new safety and effectiveness issues when used as instructed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 5 2002

Mr. Anil Bhalani
Applied Medical Resources Corporation
22872 Avenida Empressa
Rancho Santa Margarita, California 92688

Re: K020435
Trade/Device Name: Applied Medical Resources Corporation
Regulation Number: 878.4370
Regulation Name: Surgical Drape
Regulatory Class: II
Product Code: KKX
Dated: February 6, 2002
Received: February 8, 2002

Dear Mr. Bhalani:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Applied Medical Resources is providing this separate cover page for the Wound Retractor's "Indications for Use" as required.

510(k) Number: K020435

Device Name: Wound Retractor

Indications for Use: The Applied Wound Retractor is indicated for use to retract and protect an incision in the abdominal wall during both laparoscopic and open surgery. It is intended to allow the surgeon to access the abdominal cavity during surgery through an atraumatically retracted wound, providing maximum exposure with minimum incision size. In addition to incision retraction, it is intended to protect against wound contamination during both laparoscopic and open surgery.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The -Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
General Hospital Devices
K020435